



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) Publication number : **0 462 702 B1**

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication of patent specification :
16.02.94 Bulletin 94/07

(51) Int. Cl.⁵ : **A61B 5/14, A61M 5/31**

(21) Application number : **91304532.4**

(22) Date of filing : **20.05.91**

(54) **Sealing filter cap for syringe.**

(30) Priority : **19.06.90 US 540159**

(43) Date of publication of application :
27.12.91 Bulletin 91/52

(45) Publication of the grant of the patent :
16.02.94 Bulletin 94/07

(84) Designated Contracting States :
DE DK ES FR GB IT NL SE

(56) References cited :
**EP-A- 0 060 385
EP-A- 0 081 655
EP-A- 0 321 358
GB-A- 2 176 710
US-A- 4 043 334
US-A- 4 769 026**

(73) Proprietor : **SMITHS INDUSTRIES MEDICAL
SYSTEMS INC.
15 Kit Street, P.O. Box 724
Keene, New Hampshire 03431-0724 (US)**

(72) Inventor : **Bell, Craig James
27, Meadow Road, East Swanzey
Winchester, New Hampshire, 03470 (US)**

(74) Representative : **Flint, Jonathan McNeill
SMITHS INDUSTRIES PUBLIC LIMITED
COMPANY 765 Finchley Road
London NW11 8DS (GB)**

EP 0 462 702 B1

Note : Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Description

This invention relates to assemblies of the kind comprising a syringe having a nose through which liquid is drawn into and ejected from the syringe and a cap fitted in a gas-tight manner on the nose of the syringe after having drawn liquid into the syringe to prevent escape of liquid from the assembly, the cap being removable subsequently to enable ejection of liquid through the nose of the syringe.

It is known, such as from US-A-4,043,334, to provide a cap for a syringe to prevent escape of liquid such as disclosed in the preamble of claim 1.

There are many instances in which air can contaminate an arterial blood gas sample. For example, aspiration of a sample through a needle or the incomplete filling of a syringe may draw air into the syringe. Because the purpose of withdrawing the blood is to evaluate the patient's blood gas levels (e.g., carbon dioxide and oxygen) or variables which depend upon blood gas levels (e.g., pH), the introduction of air into the sample would serve to alter the true concentrations in the blood and cause subsequent analysis of data to be misleading.

One technique for removing air from a freshly-filled syringe is to tilt the syringe upward so that air bubbles rise to the top, cradle the open-ended head or nose of the syringe (called the "luer") with a piece of gauze, and advance the syringe plunger so that air is expelled. Although this technique works well in removing air from the syringe, it may also cause some blood to be expelled. For example, blood may be expelled either if the plunger is pushed too aggressively or if blood is trapped by capillarity in the uppermost portion of the luer. Thus, the present air removal technique poses an unacceptable risk in exposing workers to blood which may contain any number of biohazards.

Most prior art dealing with the air-contamination problem concentrated on expelling contaminating air from the syringe while the syringe was being filled with the patient's blood (Bailey, U.S. Pat. No. 3,978,846 and Rattenborg, U.S. Pat. No. 4,340,067). These systems incorporate hydrophilic filters into the body of the syringe. When dry, a hydrophilic filter allows air to pass through it and out of the syringe. The syringe-filter system fills with blood because a pressure differential between the luer opening and the filter is created by the patient's arterial pressure. This differential helps force air through the filter and out of the syringe. When all of the air is expelled, the leading edge of the blood contacts the filter. When wetted by the blood, the hydrophilic nature of the filter causes it to expand and prohibit passage of both air and liquid. The utility of these hydrophilic systems, however, does not extend to post-filling contaminations because the already-wetted filter will no longer pass air and so it can not be utilized to purge air introduced at later times.

Hydrophobic filters which prevent passage of air and liquid when wet are also known for venting medical liquid systems such as described in EP-A-0081655.

The U.S. Pat. Nos. 4,769,026 and 4,775,376 of Strung disclose devices that address the problems of post-filling contamination. These devices utilize separate containers equipped with hydrophobic filters. Hydrophobic filters allow for the passage of air but not liquid. Once the container and syringe are attached in an airtight fit, air and blood from the syringe are injected into this separate container by advancing the syringe plunger until no more air remains in the syringe. There are, however, two weaknesses to this type of system. First, the device's filter will always permit air passage, even when wet. Thus, preparation, transport and handling of the syringe-needle-device unit may engender the threat of air re-entry through the filter. Second, the device uses a rubber stopper to connect the needle of the syringe and the barrel of the device. The disadvantage of this system is that the needle is still connected to the syringe. Thus, preparation, transport, handling and management of the unit may pose unacceptable risks of needle prick.

It is an object of the present invention to provide a cap that will allow gas to be purged from a syringe whilst preventing escape of liquid.

According to one aspect of the present invention there is provided an assembly of the above-specified kind characterised in that the flow preventer allows free flow of gas through the housing when dry but prevents gas flow through the housing when wet.

This new cap advantageously allows for flexible management of the syringe in post-filling situations by allowing for needle removal and expulsion of post-filling air.

The flow preventer may include a hydrophilic filter such as of porous polyethylene impregnated with cellulose. The housing may be configured to prevent liquid from completely wetting the flow preventer before all the gas is purged from the fluid container. The housing may include a flow restricting portion of reduced cross-section located between the one end of the housing and the flow preventer and spaced from the flow preventer, and a reservoir open to the flow restricting portion, the reservoir being sufficient to hold all the liquid which passes through the flow restricting portion before all the gas is purged from the fluid container. The filter preferably has a portion exposed to fluid directly expelled through the flow restricting portion and other portions recessed away from the flow restricting portion. The hydrophilic filter may have a convex face, the flow restricting portion being aligned centrally of the convex face. The housing is preferably transparent.

According to another aspect of the present invention there is provided a method of purging gas from an arterial blood gas sample in a syringe, including the steps of removing a needle from the nose of the syringe after having drawn blood into the syringe through the nose, characterised in that the method includes attaching to the nose of the syringe a vented cap including a flow preventer that prevents liquid flow and allows free flow of gas when dry but prevents flow of gas when wet, holding the capped syringe with its capped end above its plunger, and advancing the plunger within the syringe to expel gas and blood from the nose of the syringe until blood contacts the flow preventer and causes it to become sealed, such that gas escapes through the flow preventer and blood is prevented from escaping by the flow preventer.

A self-sealing cap for a syringe, in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a cross-sectional view of the syringe tip cap of the present invention;

Figure 2 is a partially sectioned view of a typical syringe;

Figure 3 is a cross-sectional view of the syringe tip cap of Figure 1 attached to a typical syringe; and

Figure 4 is a cross-sectional view of an alternative embodiment of the syringe tip cap of the present invention with a partially cross-sectioned filter attached to a typical syringe.

With reference first to Figure 1, the main body of the syringe tip cap is a tubular housing or member 1 of circular transverse cross-section, one end 2 of which is open and fitted on the inside with a groove 3 to accommodate the threaded ring of a luer lock found on some syringes. This end of the member thus defines a fluid-tight connection when it attaches to the male-luer design of a syringe. The other end 4 of the member is virtually closed, except for a vent hole 5 in the middle of the cross-section. Two 360 degree shoulders 90 extend from the virtually closed end 4 of the tubular member 1 and the open end 2 to facilitate handling and manufacturing the syringe tip cap.

Abutting the interior face of the virtually closed end 4 of the tubular member 1 is a flow preventer in the form of disc-like hydrophilic filter 6. The filter is secured in place circumferentially by making it slightly oversized so that it fits the inner wall of the tubular member 7 tightly. Additionally, notches 8 can be placed on the inside surface of the tubular member section which contact the filter 6 to ensure the tight fit.

The filter 6 in the preferred embodiment is comprised of porous polyethylene impregnated with cellulose. It is preferred that the tubular member 1 be made of a non-reactive clear plastic. The clarity of the plastic enables the operator visually to monitor the wetting of the filter 6. The inert quality is necessary because the blood sample's characteristics should not be altered merely by its presence in the tubular member 1.

A syringe 50, shown in Figure 2, is of standard tubular design fitted with a plunger 51 slidably received therein so that the inside walls of the tube or barrel and the outer edge of the plunger 51 produce a tight fit around the circumference of the plunger 51. Typical use of the syringe 50 causes a blood sample to become exposed to a certain amount of air. In order to make use of the syringe cap of the present invention, the needle 52 is unscrewed from the syringe 50 using a sheath after a blood sample has been taken. The syringe tip cap is then screwed onto the luer 53 of the syringe 50. The male luer lock of the syringe securely mates with the female luer lock 3 of the syringe tip cap. Alternatively, the connection can be secured by a friction fit between the outer circumference of the syringe tip and the inner circumference of the cap. Once the syringe tip cap is set securely onto the syringe luer 53, as shown in FIG. 3, an airtight fit is obtained. The syringe is now held so the filter tip cap is pointing up to cause the air to rise to the luer end. The plunger 51 in the syringe 50 is advanced and the air is expelled from the syringe 50 into the syringe tip cap. Because the filter 6 is dry at this time, the air may easily pass through the filter 6 and vent hole 5. Following the air into the syringe tip cap is the leading edge of the blood sample. This blood is pushed forward through the luer 53 and eventually advances all the way up to the filter 6. When the blood contacts the filter 6, the hydrophilic nature of the filter 6 causes it to expand. This expansion serves to prevent air and liquid flow through its axial cross-section. The capped syringe then contains an air free sample sealed against further contamination.

It may be more difficult to expel all of the air if there is blood in the syringe's luer section 53. This blood ('luer blood') is not displaced when the air rises to that end. The luer blood is the first fluid to leave the syringe 50 and contact the filter 6. If the amount of luer blood contacting the filter 6 prior to complete air passage is significant, it may cause the filter 6 to expand and seal off before all the air is purged from the syringe 50.

Referring now to Figure 4, an improved and preferred tip cap is illustrated. The presently preferred embodiment incorporates a cylindrical axial flow restrictor or choke 10 which serves to narrow the flow cross-section of the blood prior to contacting the filter. In addition, the preferred cap also utilizes a convex, or bullet tip, filter 75. This type of filter 75 is configured to reduce the chances of wetting the entire front edge of the filter 75 before all the air is evacuated. Tabs 92 extend outwardly from the tubular member 1. The tabs 92 are used when applicable to engage the threads of a luer lock ring on a syringe.

The more narrow diameter of the choke outlet 10 restricts the area in which the blood initially strikes the filter 75 to a small circumference directly in the middle of the filter 75 cross section. A cavity 9 is formed between

the choke output 10 and the filter 6. The cavity 9 is extended down around the circumference of the choke 10 to form a reservoir 11. Thus, the central extended portion of the filter 75 is aligned with the opening in the choke while the recessed portion of the filter, which in this design is the outer annulus, is recessed away from the opening. The recessed portion of the filter is not exposed to liquid as it is expelled from the choke, but only to liquid as the cavity 9 is filled. The reservoir 11 fills with the initial blood expelled from the choke 10, leaving the outer annulus of the filter 75 dry so that air can escape. Thus, when the luer blood is expelled through the choke 10, some may strike the filter 75 and that which does not wet the filter 75 drops to the sides and collects in the reservoir 11. Because the volume of the reservoir 11 is greater than the volume of the syringe's luer volume 53, the reservoir 11 is of sufficient size to collect any of the luer blood which does not initially wet the filter 75. The combination of the reservoir 11 and the choke 10 serves to keep major portions of the filter 75 dry until all the air in the syringe 50 has passed through. Once all the air has passed, the blood from the main body of the syringe 50 enters the syringe tip cap, passes through the choke 10 and into the reservoir 11 and raises the level of blood in the reservoir 11 up to the filter 75. When the cavity 9 is filled with blood, the entire filter 75 surface is wetted and the filter 75 is sealed.

Of course, it should be understood that various changes and modifications to gas purging device described above will be apparent to those skilled in the art. For example, any number of wall shapes, openings and filter configurations may be used to achieve a device which permits all of the contaminant air to be expelled before all portions of the filter have been sealed. Also, the invention need not be restricted to procedures involving blood or to syringes. Many types of hazardous liquid in different fluid containers may be handled by this method. These and other changes can be made without departing from the scope of the invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the following claims.

25

Claims

1. An assembly comprising a syringe (50) having a nose (53) through which liquid is drawn into and ejected from the syringe and a cap fitted in a gas-tight manner on the nose of the syringe after having drawn liquid into the syringe to prevent escape of liquid from the assembly, the cap being removable subsequently to enable ejection of liquid through the nose of the syringe, the cap including a tubular housing (1) including a flow preventer (6, 75) fixed in the housing between its ends, and preventing liquid flow through the housing (1) characterised in that the flow preventer (6, 75) allows free flow of gas through the housing (1) when dry but prevents gas flow through the housing when wet.
2. An assembly according to Claim 1, characterised in that the flow preventer includes a hydrophilic filter (6, 75) of porous polyethylene impregnated with cellulose.
3. An assembly according to Claim 1 or 2, characterised in that the housing (1) is configured to prevent liquid from completely wetting the flow preventer (75) before all the gas is purged from the fluid container (50).
4. An assembly according to Claim 3, characterised in that the housing (1) includes a flow restricting portion (10) of reduced cross-section located between the one end of the housing (1) and the flow preventer (75) and spaced from the flow preventer, and a reservoir (11) open to the flow restricting portion (10), and that the reservoir (11) is sufficient to hold all the liquid which passes through the flow restricting portion (10) before all the gas is purged from the fluid container (50).
5. An assembly according to Claim 4 in which the flow preventer includes a hydrophilic filter, characterised in that the filter (75) has a portion exposed to fluid directly expelled through the flow restricting portion (10) and other portions recessed away from the flow restricting portion (10).
6. An assembly according to Claim 5, characterised in that the hydrophilic filter (75) has a convex face, and that the flow restricting portion (10) is aligned centrally of the convex face.
7. An assembly according to any one of the preceding claims, characterised in that the housing (1) is transparent.
8. A method of purging gas from an arterial blood gas sample in a syringe, including the steps of removing a needle (52) from the nose (53) of the syringe (50) after having drawn blood into the syringe through the nose (53), characterised in that the method includes attaching to the nose (53) of the syringe (50) a

vented cap (1) including a flow preventer (6, 75) that prevents liquid flow and allows free flow of gas when dry but prevents flow of gas when wet, holding the capped syringe (50) with its capped end above its plunger (51), and advancing the plunger within the syringe to expel gas and blood from the nose (53) of the syringe until blood contacts the flow preventer (6, 75) and causes it to become sealed, such that gas escapes through the flow preventer (6, 75) and blood is prevented from escaping by the flow preventer (6,75).

10 Patentansprüche

1. Anordnung aus einer Spritze (50) mit einer Nase (53), durch welche Flüssigkeit in die Spritze eingesaugt und aus dieser ausgestoßen werden kann und einer Kappe, welche gasdicht auf die Nase der Spritze gesetzt wird nachdem Flüssigkeit in die Spritze eingesaugt wurde, um das Entweichen von Flüssigkeit aus der Anordnung zu verhindern, wobei die Kappe anschließend entfernbar ist, um den Ausstoß der Flüssigkeit durch die Nase der Spritze zu ermöglichen und die Kappe ein röhrenförmiges Gehäuse (1) aufweist, welches einen Flußverhinderer (6, 75) umfaßt, der in dem Gehäuse zwischen seinen Enden fixiert ist und den Durchfluß von Flüssigkeit durch das Gehäuse (1) verhindert, **dadurch gekennzeichnet**, daß der Flußverhinderer (6, 75) den freien Durchfluß von Gas durch das Gehäuse (1) ermöglicht, wenn er trocken ist, jedoch den Gasdurchfluß durch das Gehäuse verhindert, wenn er naß ist.
2. Anordnung nach Anspruch 1, **dadurch gekennzeichnet**, daß der Flußverhinderer ein hydrophiles Filter (6, 75) aus porösem, mit Cellulose imprägniertem Polyäthylen umfaßt.
3. Anordnung nach Anspruch 1 oder 2, **dadurch gekennzeichnet**, daß das Gehäuse (1) so ausgestaltet ist, daß die Flüssigkeit den Flußverhinderer (75) nicht vollständig benetzen kann, bevor das gesamte Gas aus dem Flüssigkeitsbehälter (50) entfernt ist.
4. Anordnung nach Anspruch 3, **dadurch gekennzeichnet**, daß das Gehäuse (1) einen Flußeinschränkungsbereich (10) reduzierten Querschnitts aufweist, welcher sich zwischen dem einen Ende des Gehäuses (1) und dem Flußverhinderer (75) und im Abstand von dem Flußverhinderer befindet, und ein Reservoir (11), welches zu dem Flußeinschränkungsbereich (10) hin geöffnet ist, wobei das Reservoir (11) ausreichend groß ist, um die gesamte Flüssigkeit zu beinhalten, welche durch den Flußeinschränkungsbereich (10) strömt, bevor das gesamte Gas aus dem Flüssigkeitsbehälter (50) entfernt ist.
5. Anordnung nach Anspruch 4, wobei der Flußverhinderer ein hydrophiles Filter umfaßt, **dadurch gekennzeichnet**, daß das Filter (75) einen Bereich aufweist, welcher der direkt aus dem Flußeinschränkungsbereich (10) austretenden Flüssigkeit ausgesetzt ist und weitere Bereiche, welche gegenüber dem Flußeinschränkungsbereich (10) zurückgesetzt sind.
6. Anordnung nach Anspruch 5, **dadurch gekennzeichnet**, daß das hydrophile Filter (75) eine konvexe Oberfläche hat und daß der Flußeinschränkungsbereich (10) zentral zu der konvexen Oberfläche angeordnet ist.
7. Anordnung nach einem der voranstehenden Ansprüche, **dadurch gekennzeichnet**, daß das Gehäuse (1) transparent ist.
8. Verfahren zur Entfernung von Blut aus einer arteriellen Blutgasprobe in einer Spritze, wobei eine Kanüle (52) von der Nase (53) der Spritze (50) entfernt wird, nachdem Blut durch die Nase (53) in die Spritze eingesaugt wurde, **dadurch gekennzeichnet**, daß das Verfahren beinhaltet: das Anbringen einer belüfteten Kappe (1) auf der Nase (53) der Spritze (50), wobei diese Kappe einen Flußverhinderer (6, 75) umfaßt, welcher den Flüssigkeitsdurchfluß verhindert und den freien Gasdurchfluß erlaubt, wenn er trocken ist, jedoch den Durchfluß von Gas verhindert, wenn er naß ist, das Halten der mit der Kappe versehenen Spritze (50) mit dem Kappenende über ihren Kolben (51), und das Bewegen des Kolbens innerhalb der Spritze zur Austreibung von Gas und Blut durch die Nase (53) der Spritze bis das Blut in Kontakt mit dem Flußverhinderer (6, 75) gerät und diesen zur Abdichtung führt, so daß Gas durch den Flußverhinderer (6, 75) entweichen kann und der Flußverhinderer (6, 75) Blut am Entweichen hindert.

Revendications

1. Ensemble comprenant une seringue (50), pourvue d'un bec (53) à travers lequel un liquide est tiré dans la seringue et en est éjecté, et d'un capuchon ajusté d'une manière étanche aux gaz sur le bec de la seringue pour empêcher une fuite de liquide de l'ensemble après qu'on ait tiré du liquide dans la seringue, le capuchon étant amovible ultérieurement pour permettre une éjection de liquide à travers le bec de la seringue, le capuchon comportant un corps tubulaire (1) pourvu d'un organe de prévention d'écoulement (6, 75) qui est fixé dans le corps entre les extrémités de celui-ci et qui empêche un écoulement de liquide à travers le corps (1), caractérisé en ce que l'organe de prévention d'écoulement (6, 75) permet un libre écoulement de gaz à travers le corps (1) quand il est sec, mais empêche l'écoulement de gaz à travers le corps quand il est humide.
2. Ensemble selon la revendication 1, caractérisé en ce que l'organe de prévention d'écoulement comporte un filtre hydrophile (6, 75) en polyéthylène poreux imprégné de cellulose.
3. Ensemble selon la revendication 1 ou 2, caractérisé en ce que le corps (1) est configuré de façon à empêcher que du liquide humidifie complètement ledit organe (75) avant que tout le gaz soit évacué du conteneur de fluide (50).
4. Ensemble selon la revendication 3, caractérisé en ce que le corps (1) comporte une zone de restriction d'écoulement (10) à section transversale réduite, située entre une première extrémité du corps (1) et l'organe de prévention d'écoulement (75) et distante de cet organe, et un réservoir (11) ouvert vers la zone de restriction d'écoulement (10), et en ce que le réservoir (11) est suffisant pour contenir tout le liquide qui passe à travers la zone de restriction d'écoulement (10) avant que tout le gaz soit évacué du conteneur de fluide (50).
5. Ensemble selon la revendication 4, dans lequel l'organe de prévention d'écoulement comporte un filtre hydrophile, caractérisé en ce que le filtre (75) comporte une partie exposée au fluide directement expulsé à travers la zone de restriction d'écoulement (10) et d'autres parties situées en retrait de la zone de restriction d'écoulement (10).
6. Ensemble selon la revendication 5, caractérisé en ce que le filtre hydrophile (75) a une face convexe et en ce que la zone de restriction d'écoulement (10) est alignée sur le centre de ladite face convexe.
7. Ensemble selon l'une des revendications précédentes, caractérisé en ce que le corps (1) est transparent.
8. Procédé pour évacuer du gaz d'un échantillon de sang artériel dans une seringue, comprenant les étapes consistant à enlever une aiguille (52) du bec (53) de la seringue (50) après avoir tiré du sang dans la seringue à travers le bec (53), caractérisé en ce que le procédé consiste en outre à fixer au bec (53) de la seringue (50) un capuchon à évent (1) comportant un organe de prévention d'écoulement (6, 75) qui empêche un écoulement de liquide et permet un libre écoulement de gaz quand il est sec, mais empêche l'écoulement de gaz quand il est humide, à tenir la seringue (50) de façon que son extrémité munie du capuchon se trouve au-dessus de son piston (51) et faire avancer le piston dans la seringue pour expulser du gaz et du sang par le bec (53) de la seringue jusqu'à ce que le sang touche l'organe de prévention d'écoulement (6, 75) et le fasse devenir étanche, de sorte que le gaz s'échappe à travers l'organe de prévention d'écoulement (6, 75) et que le sang est empêché de s'échapper par cet organe (6, 75).

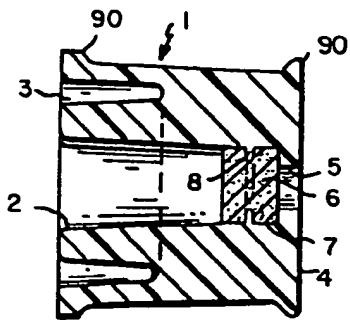


FIG. 1

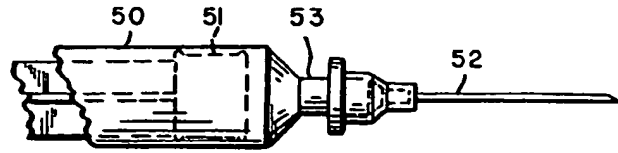


FIG. 2

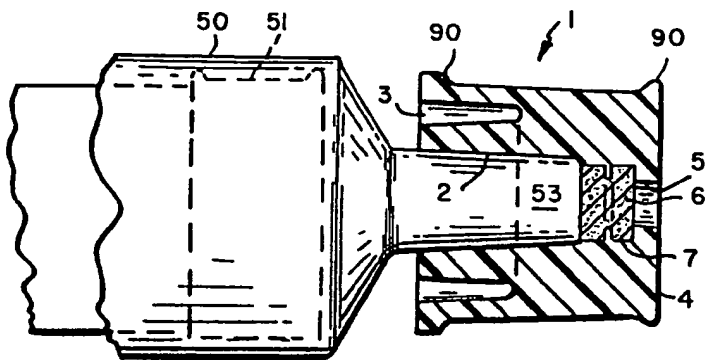


FIG. 3

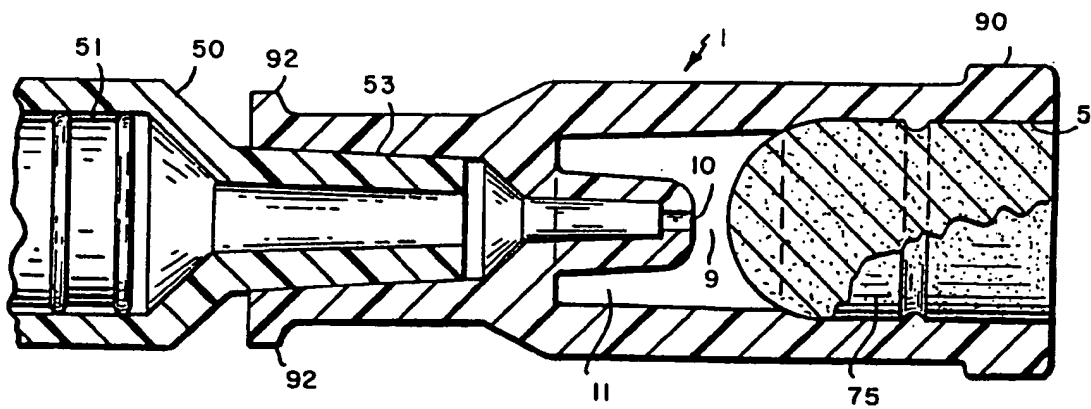


FIG. 4